Application of

Hugh R. Sharkey

and

Alexander Khairkhahan

for

UNITED STATES LETTERS PATENT

on

INFLATABLE VENTRICULAR PARTITIONING DEVICE

Drawings: Four (4) Sheets
Atty. Docket No.: R0395.00900

Duane Morris LLP
One Market, Spears Tower, Suite 2000
San Francisco, CA 94105-1104
(415) 317-2200

INFLATABLE VENTRICULAR PARTITIONING DEVICE

FIELD OF THE INVENTION

[0001] The present invention relates generally to the field of treating congestive heart failure and more specifically, to a device and method for partitioning a patient's heart chamber and a system for delivering the treatment device.

BACKGROUND OF THE INVENTION

[0002] Congestive heart failure (CHF) is characterized by a progressive enlargement of the heart, particularly the left ventricle and is a major cause of death and disability in the United States. Approximately 500,000 cases occur annually in the U.S. alone. As the patient's heart enlarges, it cannot efficiently pump blood forward with each heart beat. In time, the heart becomes so enlarged the heart cannot adequately supply blood to the body. Even in healthy hearts only a certain percentage of the blood in a patient's left ventricle is pumped out or ejected from the chamber during each stroke of the heart. The pumped percentage, commonly referred to as the "ejection fraction", is typically about sixty percent for a healthy heart. A patient with congestive heart failure can have an ejection fraction of less than 40% and sometimes lower. As a result of the low ejection fraction, a patient with congestive heart failure is fatigued, unable to perform even simple tasks requiring exertion and experiences pain and discomfort. Further, as the heart enlarges, the internal heart valves such as the mitral valve, cannot adequately close. An incompetent mitral valve allows regurgitation of blood from the left ventricle back into the left atrium, further reducing the heart's ability to pump blood forewardly.

[0003] Congestive heart failure can result from a variety of conditions, including viral infections, incompetent heart valves (e.g. mitral valve), ischemic conditions in the heart wall or a combination of these conditions. Prolonged ischemia and occlusion of coronary arteries can result in myocardial tissue in the ventricular wall dying and becoming scar tissue. Once the myocardial tissue dies, it is less contractile (sometimes non-contractile) and no longer contributes to the pumping action of the heart. It is referred to as hypokinetic. As the disease progresses, a local area of compromised myocardium may bulge out during the heart contractions, further decreasing the heart's ability to pump blood and further reducing the ejection fraction. In this instance, the heart wall is referred to as dyskinetic or akinetic. The dyskinetic region of the heart wall may stretch and eventually form an aneurysmic bulge.

[0004] Patients suffering from congestive heart failure are commonly grouped into four classes, Classes I, II, III and IV. In the early stages, Classes I and II, drug therapy is presently the most commonly prescribed treatment. Drug therapy typically treats the symptoms of the disease and may slow the progression of the disease, but it can not cure the disease. Presently, the only permanent treatment for congestive heart disease is heart transplantation, but heart transplant procedures are very risky, extremely invasive and expensive and are performed on a small percentage of patients. Many patient's do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria, and, Furthermore, there are not enough hearts available for transplant to meet the needs of CHF patients who do qualify.

[0005] Substantial effort has been made to find alternative treatments for congestive heart disease. For example, surgical procedures have been developed to dissect and

remove weakened portions of the ventricular wall in order to reduce heart volume. This procedure is highly invasive, risky and expensive and is commonly only done in conjunction with other procedures (such as heart valve replacement or coronary artery by-pass graft). Additionally, the surgical treatment is usually limited to Class IV patients and, accordingly, is not an option for patients facing ineffective drug treatment prior to Class IV. Finally, if the procedure fails, emergency heart transplant is the only presently available option.

[0006] Other efforts to treat CHF include the use of an elastic support, such as an artificial elastic sock placed around the heart to prevent further deleterious remodeling.

[0007] Additionally, mechanical assist devices have been developed as intermediate procedures for treating congestive heart disease. Such devices include left ventricular assist devices and total artificial hearts. A left ventricular assist device includes a mechanical pump for increasing blood flow from the left ventricle into the aorta. Total artificial heart devices, such as the Jarvik heart, are usually used only as temporary measures while a patient awaits a donor heart for transplant.

[0008] Recently, improvements have been made in treating patient's with CHF by implanting pacing leads in both sides of the heart in order to coordinate the contraction of both ventricles of the heart. This technique has been shown to improve hemodynamic performance and can result in increased ejection fraction from the right ventricle to the patient's lungs and the ejection fraction from the left ventricle to the patient's aorta. While this procedure has been found to be successful in providing some relief from CHF symptoms and slowed the progression of the disease, it has not been able to stop the disease.

SUMMARY OF INVENTION

[0009] The present invention is directed to a ventricular partitioning device and method of employing the device in the treatment of a patient with congestive heart failure. Specifically, the ventricular chamber of the CHF patient is partitioned by the device so as to reduce its total volume and to reduce the stress applied to the heart and, as a result, improve the ejection fraction thereof.

[0010] A ventricular partitioning device embodying features of the invention has an inflatable partitioning element, which is configured to partition the patient's ventricular heart chamber into a main productive portion and a secondary non-productive portion. The inflatable partitioning element may be at least in part disc shaped and hollow. The partitioning device preferably has a supporting or spacing element extending from the distal side of the inflatable partitioning element for non-traumatically engaging a region of the patient's ventricular wall defining in part the secondary non-productive portion to space a central portion of the partitioning element from the heart wall. The supporting or spacing element may itself be inflatable and preferably has an interior in fluid communication with the interior of the partitioning element.

[0011] The supporting element of the device has a length configured to extend to the heart wall, supporting and spacing the partitioning element from the heart wall. The supporting element may have an inner lumen extending therein for delivery of therapeutic or diagnostic agents through the ports provided along the length thereof.

[0012] The partitioning device may be delivered percutaneously or intraoperatively. It is relatively easy to install and provides substantial improvement in the ejection fraction of the patient's heart chamber. A suitable delivery system is described in co

pending application Serial No. 10/212032, filed on August 1, 2002 which is incorporated herein in it's entirety. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1A is a perspective view of a ventricular partitioning device in an inflated state embodying features of the invention.

[0014] Figure 1B is a perspective view of a ventricular portioning device in a deflated state embodying features of the invention.

[0015] Figure 1C is an enlarged view of the encircled region of figure 1B

[0016] Figure 2 Is a schematic view of a patient's left ventricular chamber illustrating the partitioning device shown in Figure 1A disposed within the chamber separating a working portion of the chamber from a non-working portion of the chamber.

[0017] Figure 3 is a perspective view of an alternative design of the partitioning device without a supporting member.

[0018] Figure 4 is a schematic view of a patient's left ventricular chamber illustrating the partitioning device being deployed on a delivery system.

[0019] Figure 5 is a schematic view of the patient's left ventricular chamber illustrating the partitioning device Shown in Figure 3 disposed within the chamber separating a working portion of the chamber from a non-working portion of the chamber.

[0020] Figure 6 is an elevational view of a delivery system for the partitioning device shown in Figure 3 with the inflatable partitioning element in a deflated condition.

[0021] Figure 7 is an elevational view of a delivery system as shown in Figure 6 with the partitioning element in an inflated condition.

[0022] Figure 8 is a perspective view of an alternative partitioning device which has an elongated, distally extending stem with non-traumatic bumper elements on the distal extremity.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0023] Figures 1A and 1B illustrate a partitioning device **10** which embodies features of the invention and which includes an inflatable partitioning element **12** and an inflatable supporting element **14**. The partitioning element **12** may contain anchoring members **16** around its edge **18** to engage the heart wall **20** upon expansion. The partitioning device **10** is delivered in a deflated form through a catheter. The inflatable partitioning element may be disc shaped and hollow. When inflated the supporting element **14** extends distally from the center of the partitioning element **12** and has a distal end **22** which provides a yielding engagement with a heart wall **20** when deployed within a patient's heart chamber **24**.

[0024] The partitioning element **12** has a peripheral edge **18**. The edge **18** may contain anchoring members **16** which are configured to hold the partitioning device **10** in a deployed position within the patient's heart chamber **24**. Preferably, the anchoring elements **16** penetrate into tissue of the patient's heart wall **20** in order to secure the partitioning element **12** so as to partition the ventricular chamber **24** in a desired manner. The partitioning element **12** may contain a hub **26** having a one way valve for inflation of both the partitioning element **12** and the supporting element **14**.

[0025] Figure 2 illustrates the placement of partitioning device **10** within a patient's left ventricle **24**. The partitioning element **12** partitions the patient's heart chamber **24** into a main productive portion **27** and a secondary, essentially non-productive portion **28**. The productive portion **27** is smaller than the original ventricular chamber **24** and provides for an improved ejection fraction. The partitioning increases the ejection fraction and provides an improvement in blood flow through the heart chamber. Over time, the non-productive portion **28** fills initially with thrombus and subsequently cellular growth. Bio-resorbable fillers such as polylactic acid, polyglycolic acid, polycaprolactone and copolymers and blends may be employed to fill the non-productive portion **28**. Fillers may be suitably supplied in a suitable solvent such as DMSO. Other materials which accelerate tissue growth may be deployed in the non-productive portion **28**. In some embodiments the supporting element **14** may fill a portion or all of the non-productive chamber **28**.

[0026] An alternative partitioning device **30** is shown in Figure 3 wherein the inflatable partitioning element **32** is held in place by anchoring members **34** disposed about the periphery **36**. In this embodiment the partitioning element **32** does not have a distal supporting element extending from it's distal face **38**. The proximal face **40** has a hub **42** which has a inflation port for injection inflation fluid into the interior of the element **32**.

[0027] A suitable delivery system for the partitioning devices described above is described in co-pending application Serial No. 10/212032 filed on August 1. 2002 which is incorporated herein in its entirety. Figures 4, 6 and 7 illustrate a suitable delivery system **44** with a partitioning device **30** as shown in Figure 3. The delivery system **44**

includes a control handle **46** with a delivery catheter **48** and a detachment mechanism including coil **50** secured to the distal end of the delivery catheter for releasing the partitioning device **30** from the delivery system **44** The delivery catheter **48** may be provided with an inner lumen (not shown) through which therapeutic or diagnostic fluids may be delivered. The delivery catheter **48** extends through the handle **50** and the proximal end of the catheter **48** is connected to a balloon inflation port **52**.

[0028] As shown in Figure 4, the delivery system **44** may be introduced into a patient's body through a percutaneously introduced guide catheter or cannula **54** which has an inner lumen (not shown). The partitioning device **30** is slidably disposed within the inner lumen of guide catheter **54**. The delivery system **44** is advanced distally within the inner lumen of the guide catheter **54** and engages the ventricular wall **56**. With the delivery system **44** held in place, the partitioning element **32** is inflated and the anchoring members **34** penetrate into tissue of the patient's heart wall **56,** as shown in Figure 5, to secure the partitioning device **30** within the patient's heart chamber **58** to partition the chamber into productive portion **60** and non-productive portion **62**. The delivery system **44** and the guide catheter **54** may then be removed from the patient. The proximal end of the guide catheter **54** is provided with an injection port **64** to inject therapeutic or diagnostic fluids through the inner lumen thereof into the patient's heart chamber **58**.

[0029] Figure 8 illustrates another alternative inflatable partitioning device **70** which has a partitioning element **72** and a stem **74** which extends distally from the distal face **76** of the partitioning element. The distal extremity of the stem **74** has three J-shaped bumpers **78** which allow for non-traumatic engagement with the wall of the patient's

non-productive portion of the heart chamber. A variety of other non-traumatic bumpers may be employed, such as those described in co-pending application Serial No. , which was filed on January 9, 2004 and which was entitled "VENTRICULAR PARTITIONING DEVICE". This application has been assigned to the present assignee and is incorporated herein in its entirety. The periphery of partitioning element **72** is provided with a plurality of anchoring elements **80** for securing the device to the ventricular wall. A hub **82** is provided on the proximal face **84** of the partitioning element **72** for delivery and inflation of the partitioning element as previously described.

[0030] To assist in properly locating the partitioning device during advancement and placement thereof into a patient's heart chamber, it may be provided with markers at desirable locations that provide enhanced visualization by eye, by ultrasound, by X-ray, or other imaging or visualization means. Radiopaque markers may be made with, for example, stainless steel, platinum, gold, iridium, tantalum, tungsten, silver, rhodium, nickel, bismuth, other radiopaque metals, alloys and oxides of these metals.

[0031] The partitioning device **10, 30** and **70** may be formed of suitable biocompatitble polymeric material which include expanded polytetrfluoroethylene (ePTFE), polyethylene terephthalate (PET), polyesters such as Hytrel®, polyamides such as Nylon and polyurethane. The compliance may range from about 50 to about 1000%. The inflatable partitioning element of the device in the expanded configuration has radial dimensions from about 5 to about 60 mm, preferably about 20 to about 50 mm, as measured from the center line axis. The aspect ratio of the thickness of the inflatable partitioning element at its thickest portion to the diameter of the inflatable partitioning element is from about 1:10 to about 1:1, preferably about 1:10 to about 1:2.

[0032] The delivery catheter and the guide catheter may be formed of suitable high strength polymeric material such as PEEK (polyetheretherketone), polycarbonate, PET, Nylon, and the like. To the extent not otherwise described herein, the various components of the partitioning device and delivery system may be formed of conventional materials and in a conventional manner as will be appreciated by those skilled in the art.

[0033] The inflatable partitioning and support elements may be inflated with a variety of fluids, preferably liquids such as saline or contrast fluids. Liquids which become more viscous or harden *in situ* may also be used. If the inflatable elements are formed of bioabsorable materials, the inflation fluid should be readily absorbed within the patient's bloodstream and should not have significant detrimental affects.

[0034] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. For example an inflatable partitioning element may be used to occlude an atrial appendage of the heart. Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is intended that this invention to be defined by the scope of the appended claims as broadly as the prior art will permit.

[0035] Terms such a "element", "member", "device", "section", "portion", "steps", "means" and words of similar import when used herein shall not be construed as

invoking the provisions of 35 U.S.C. §112(6) unless the following claims expressly use the terms "means" followed by a particular function without specific structure or "step" followed by a particular function without specific action. All patents and patent applications referred to above are hereby incorporated by reference in their entirety. Accordingly, it is not intended that the invention be limited, except as by the appended claims.